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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JONATHAN R. COPPETA, JOHN T. SANTINI, JR., and SCOTT A. UHLAND

Appeal 2008-4898
Application 10/668,573
Technology Center 3700

Decided:[1] February 5, 2009

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is an appeal under 35 U.S.C. § 134 involving claims to a device for the controlled release of chemical molecules. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

Claims 14-29, 35, 36, and 39-47 stand finally rejected and are on appeal (App. Br. 2). Claims 14 and 19 are representative and read as follows:

> 14. A device for the controlled release of chemical molecules comprising:
>
> an array of discrete microtubes constructed of a metal or an alloy, each microtube comprising a reservoir defined therein;
>
> a release formulation which comprises the chemical molecules, the release formulation being wholly contained in each reservoir;
>
> a rupturable covering which closes an opening at a first end of each reservoir; and
>
> a means for rupturing the rupturable covering and positively displacing the release formulation through the opening at the first end, to release the chemical molecules.
>
> 19. A device for the controlled release of chemical molecules comprising:
>
> an array of discrete microtubes, each microtube comprising a reservoir defined therein;
>
> a release formulation which comprises the chemical molecules, the release formulation being disposed in each reservoir;
>
> a rupturable covering enclosing a first end of each reservoir; and
>
> a means for rupturing the rupturable covering and positively displacing the release formulation through an opening at the first end, to release the chemical molecules,

> wherein the means for rupturing comprises a layer of an expanding material which can be activated to expand upon application of heat and a resistive heating element or resistive coating for heating the end of the microtube distal the rupturable covering upon application of an electric current through the resistive heating element or resistive coating, the release formulation being disposed between the layer of expanding material and the rupturable covering.

The Examiner cites the following documents as evidence of unpatentability:

Theeuwes	US 4,111,202	Sep. 5, 1978
Santini, Jr. et al.	US 5,797,898	Aug. 25, 1998
Eppstein et al.	US 6,692,456 B1	Feb. 17, 2004
Krulevitch et al.	US 7,025,323 B2	Apr. 11, 2006

The following rejections are before us for review:

Claims 14-18, 20-29, 35, 36, and 39 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Eppstein (Ans. 3-4).

Claims 19 and 42-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Krulevitch and Santini (Ans. 4-5).

Claims 40 and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Eppstein and Theeuwes (Ans. 5).

ANTICIPATION -- EPPSTEIN

ISSUE

The Examiner finds that Eppstein teaches an array of microtubes as recited in claim 14, each microtube having a reservoir and release formulation contained therein, each microtube also having a rupturable covering (Ans. 3). The Examiner further finds that Eppstein's device has "means for rupturing the covering/barrier material (e, thermal poration

element) and positively displacing the release formulation (pressure modulation activation linkages, Fig 23a and 23b, activated by a small pump, Col 29 lines 45-55)" (*id.*).

Appellants contend that Eppstein's device does not have a single means that accomplishes both the rupturing of the rupturable covering, and the positive displacement of the release formulation, as required by claim 14 (App. Br. 5-6). Moreover, Appellants argue, the Examiner has not made a prima facie case that the structures disclosed in Eppstein are equivalent to the means disclosed in the Specification as accomplishing the claimed functions (*id.* at 6-8).

The Examiner responds that the means-plus-function language in claim 14 is "open-ended because the specification gives no explicit definition of what the 'means' or their equivalents are" (Ans. 6). Rather, the Examiner urges, the Specification "uses terms like 'such as' or 'for example' when describing the means and therefore any structure which performs the same function is an equivalent" (*id.*). The Examiner concludes that it is reasonable to interpret the means recited in claim 14 as encompassing "two separate means, not a single means . . . . The applicant has not claimed or limited the means-plus-function language to be a *single* means for performing two functions" (*id.*).

Appellants reply that the Examiner erred in interpreting claim 14 as encompassing two separate means, given the Specification's disclosure of embodiments "in which the rupturing and displacement functions are *inextricably linked together*" (Reply Br. 3).

In view of the positions advanced by Appellants and the Examiner, the critical issue with respect to this rejection is whether the Examiner erred

in finding that Eppstein meets the limitation in claim 14 requiring the device to have "a means for rupturing the rupturable covering and positively displacing the release formulation through the opening at the first end."

FINDINGS OF FACT ("FF")

1. Claim 14 recites a device for the controlled release of chemical molecules. The device has an array of microtubes, each microtube having a reservoir that contains a release formulation, the chemical molecules being contained in the release formulation. Each microtube's reservoir has a rupturable covering at one end.

The device of claim 14 also has "a means for rupturing the rupturable covering and positively displacing the release formulation through the opening at the first end, to release the chemical molecules."

2. The Specification discloses a number of mechanisms that both rupture the covering at the end of the microtubes and positively displace the release formulation from the tubes.

Appellants' Figure 1A is reproduced below:

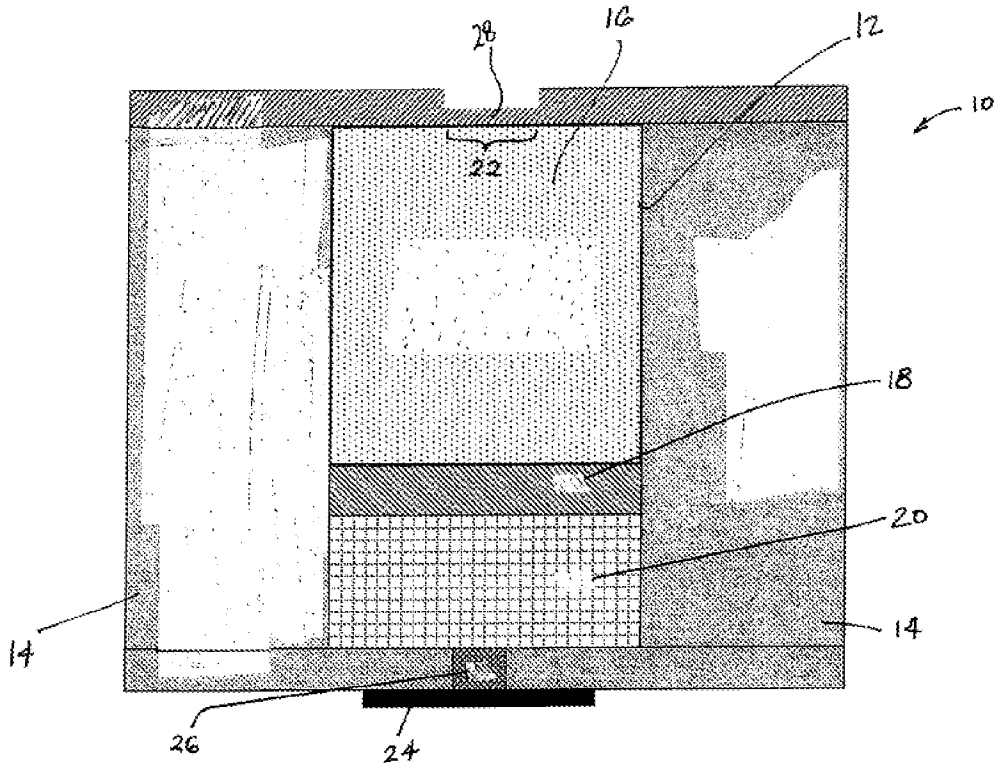


FIG. 1A

Figure 1A shows device 10, which includes "reservoir **12** [which] contains a drug formulation **16** for release. The drug formulation is adjacent the release opening **22**. A piston **18** is also provided in the reservoir. The piston **18** separates the drug formulation **16** from an osmotic pressure generating agent **20**" (Spec. 8).

The Specification discloses that "swelling of osmotic pressure generating agent **20** occurs when fluid enters through semi-permeable membrane **26**," and that, "[a]s the osmotic pressure generating agent **20** swells, pressure is generated to drive the piston **18** against the drug formulation **16**. Consequently, the drug formulation **16** is pushed out of the reservoir **12**" through release opening 22 (*id.*).

The Specification discloses that "[t]he pressure of the drug formulation **16** on the rupturable covering **28** covering the release opening **22** causes the rupturable covering **28** to rupture, allowing the drug formulation to be move from the reservoir and into surrounding environment" (*id.*).

3. Appellants' Figure 7 is reproduced below:

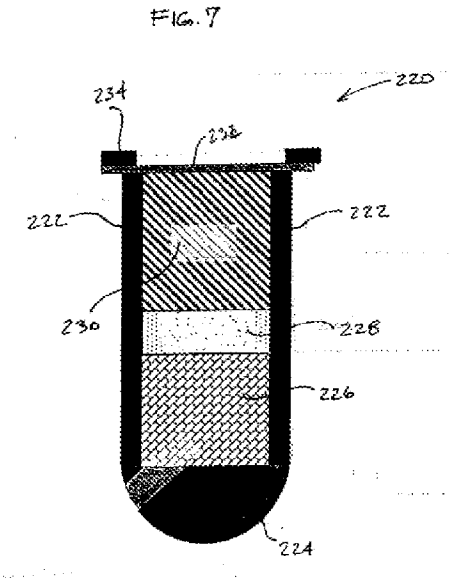


Figure 7 shows "microtube **220** [which] includes tubular structure **222** (which are the walls defining the reservoir), rupturable covering **232**, and barrier material **228**, interposed between drug formulation **230** and expansion material **226**" (Spec. 16).

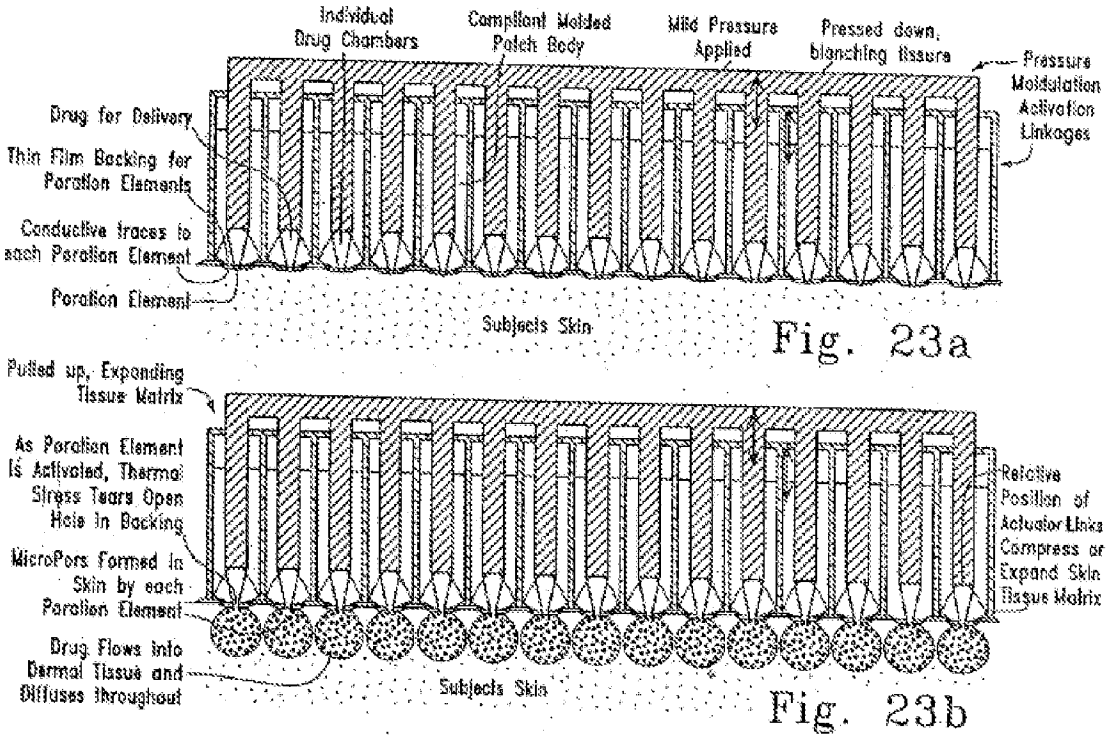
The Specification discloses that "[t]he expansion material **226** preferably is one that can be thermally activated" (*id.* at 17). The Specification further discloses that the rupturable covering 232 "ruptures to initiate release of the drug formulation from the reservoir. In one embodiment, the rupturable covering comprises or consists of a metal foil. The metal foil may be provided with one or more defects to facilitate rupture due to expansion of the expansion material" (*id.*).

4. The Specification discloses that "[i]n another embodiment, release of reservoir contents from the microtube is controlled by changing the shape of the microtube, rather than expanding a material inside the reservoir of the microtube. For example, the shape change can contract the reservoir, thereby forcing the contents of the reservoir out" (Spec. 19).

The Specification discloses that heat can be used to cause the reservoir to contract, and that, "[u]pon heating . . ., the . . . microtube undergoes a contraction that causes a hydrostatic pressure that ruptures the rupturable covering to release the drug formulation" (*id.* at 20).

5. Eppstein discloses "devices and method for the creation of small holes or perforations or micropores in biological membranes, such as the outer layers of the skin or the mucosal linings, [and] the delivery of drugs or other permeants through the micropores" (Eppstein, col. 1, ll. 15-19). One embodiment disclosed by Eppstein is a TFTI, or Thin Film Tissue Interface device, that "efficiently create[s] a pattern or array of micropores on the surface of a biological membrane" (*id.* at col. 10, ll. 10-12).

6. Figures 23a and 23b of Eppstein are reproduced below:



Figures 23a and 23b "show a cross-sectional schematic of a multi-chamber, micro-cell array that also incorporates a thermal poration element(s) at the skin contact point for each micro-cell. The multi-chamber, micro-cell array could operate by the method and principle illustrated in FIGS. **22**(*a-d*)" (Eppstein, col. 31, ll. 13-18).

7. As seen in Figures 23a and 23b, Eppstein's device includes a thin film backing for its poration elements, such that when the drug solution is to be delivered from the reservoirs, the thermal stress from the heat used to activate the porating element causes a hole to open in the backing.

8. The device shown in Figures 23a and 23b functions by placing the drug-containing reservoir adjacent to the skin of the recipient, applying pressure to the center of the reservoir to force the interstitial fluid adjacent to the reservoir away from the reservoir by "blanching" the underlying tissue,

and then pulling the reservoir away from the skin, thereby allowing the drug solution to be sucked into the skin (*see* Eppstein, Figure 22). That is, "the decompressed state of the recently blanched skin cell tissue matrix directly beneath the micropore would induce fluid from the drug reservoir to flow through the pore into these skin tissues beneath the porated surface" (*id.* at col. 28, ll. 36-40).

9. Eppstein discloses that, to coordinate its device's actions, a pre-programmed controller can be used to generate the signals needed to cycle the system through the steps required for drug delivery (Eppstein, col. 29, ll. 44-47). Eppstein states that the "controller may contain a microprocessor which would generate the appropriate sequence of control signals to enable the different functions of the system in the desired sequence. A small pump(s), such as a small diaphragm or peristaltic pump could be engaged when needed to develop a suction or pressure" (*id.* at col. 29, ll. 47-52).

10. Regarding control of its devices, Eppstein further discloses:

> Alternatively, a small pressure reservoir such as a metal or plastic cylinder or bladder of compressed gas, or a pressure produced via the electrolysis of a liquid in a closed chamber, producing gas, could be used to supply pressure. Optionally, control over all aspects of the movement of the system could easily be achieved with a simple valving mechanism(s) to provide the microprocessor coordinated control of reservoir pressure/suction and the action of a controllable actuator to provide the requisite movement of the central reservoir relative to the outer portions of the structure during the compression/decompression cycles. With suitable additional valves and seals, one could utilize the suction and pressure sources to provide the depression/withdrawal, action of the central portion from the skin surface. In this manner, a single peristaltic pump mechanism, with one or more circuits, could be engaged in either the forward or reverse direction, generating

> either pressure or suction as required, with the proper design of the swept area of the different pump circuits, and optionally, appropriately sized pressure bleed ports and one way valves, the required, coordinated, sequence of suction, pressure and mechanical translation could all be performed by a system with a single peristaltic pump based moving part. *As peristaltic pumps are by nature, a positive displacement mechanism, they are very efficient.* Alternatively, these motive forces could easily be provided by a small motor(s) or actuator(s) under microprocessor control with appropriate linkage to coordinate movements to the device cycle.

(Eppstein, col. 29, l. 52, through col. 30, l. 13 (emphasis added).)

PRINCIPLES OF LAW

Paragraph Six of 35 U.S.C. § 112 states:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Thus, "one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure." *In re Donaldson Co., Inc.,* 16 F.3d 1189, 1193 (Fed. Cir. 1994).

In order to meet a means-plus-function limitation, a "structure must either be the same as the disclosed structure or be a section 112, paragraph 6 'equivalent,' i.e., (1) perform the identical function and (2) be otherwise insubstantially different with respect to structure." *Kemco Sales, Inc. v. Control Papers Co., Inc.,* 208 F.3d 1352, 1364 (Fed. Cir. 2000). Thus, "two

structures may be 'equivalent' for purposes of section 112, paragraph 6 if they perform the identical function, in substantially the same way, with substantially the same result." *Id.*

ANALYSIS

We agree with Appellants that the Examiner erred in finding that Eppstein meets the limitation in claim 14 requiring the claimed device to have "a means for rupturing the rupturable covering and positively displacing the release formulation through the opening at the first end."

Claim 14 uses the phrase "means for," followed by a recitation of the functions that the means must accomplish, without reciting the structures or materials used to accomplish the functions (FF 1). Therefore, 35 U.S.C. § 112, sixth paragraph, requires the limitation at issue to be interpreted as covering the structure, material, or acts that the Specification describes as corresponding to the means, or equivalents thereof. *See Donaldson*, 16 F.3d at 1193.

In the instant case, the Specification discloses several mechanisms that both rupture a rupturable covering at the end of a microtube's reservoir and positively displace the release formulation through the opening at the end of the tube. Specifically, the Specification discloses that the rupturing and positive displacement can be performed by an osmotic pressure generating agent located in the reservoir behind or beneath the release formulation (FF 2). The osmotic pressure generating agent takes in fluid and swells, thereby generating sufficient pressure in the reservoir to rupture the covering at the end of the reservoir and push the release formulation through the resultant opening at the end of the reservoir (*id.*).

The Specification also discloses that a thermally activated expansion material can be used in a similar manner to create sufficient pressure to rupture the covering and positively displace the release formulation from the reservoir (FF 3). The Specification further discloses that by contracting the microtube, enough pressure can be generated in the reservoir to rupture the covering and push the release formulation from the reservoir (FF 4).

Thus, when claim 14 is viewed consistently with the Specification, it requires the device to have a single means capable of accomplishing both the rupturing of the cover and the positive displacement of the release formulation. The mechanisms disclosed in the Specification for accomplishing those functions include osmotically- or thermally-driven expansion materials that push a piston against the release formulation to create sufficient pressure in the reservoir to rupture the covering and drive the formulation out of the tube, and a thermally-driven mechanism that contracts the reservoir to create the rupturing and driving pressure (FF 2-4).

In contrast, Eppstein's device uses at least two separate means to accomplish the recited functions. Specifically, Eppstein uses a thermally activated poration device to rupture the thin film backing at the end of the microtubes (*see* FF 6-7). Separate from the thermal tearing of the covering, Eppstein uses a pushing and pulling action on its device to cause the tissue adjacent to the device to draw the fluid out of the tube (FF 8), and also discloses that "[a] small pump(s), such as a small diaphragm or peristaltic pump [which] could be engaged when needed to develop a suction or pressure" (Eppstein, col. 29, ll. 47-52 (FF 9)).

Because Eppstein uses a combination of heat-induced tearing in the tubes' film backing, along with suction to remove the drug formulation, we

agree with Appellants that the reference does not use the same structure as the expansion- or contraction-driven mechanisms described in Appellants' Specification as corresponding to the means-plus-function limitation at issue.

We also agree with Appellants that Eppstein's combination of elements is not equivalent to the structures disclosed in Appellants' Specification as corresponding to the means at issue. Specifically, to rupture the covering on its microtubes, Eppstein's device uses heat in its poration element to create thermal stress in the film backing (FF 6-7).

In contrast, Appellants' Specification discloses that the claimed rupturing and positive displacement are accomplished using mechanisms that apply pressure within the reservoir sufficient to cause the rupturable seal to burst (FF 2-4). Because we agree with Appellants that using heat to rupture the covering is substantially different than using internal pressure, we also agree with Appellants that the Examiner has not shown that the structures encompassed by claim 14 are equivalent to Eppstein's.

We note, as the Examiner points out, that Eppstein discloses that a peristaltic pump is useful in its devices (FF 9, 10). We also note that Eppstein describes a peristaltic pump as a "positive displacement mechanism" (Eppstein, col. 30, l. 9 (FF 10)).

However, even assuming for argument's sake that the peristaltic pump is used as part of the mechanism to drive the drug formulation from the microtubes, rather than to accomplish the pushing and pulling action described in Eppstein's Figure 22 (FF 8), Eppstein nonetheless discloses that its device uses a thermally-activated poration element to rupture the tubes' coverings (FF 6, 7), which is not an equivalent to the pressure-driven

structures described in Appellants' Specification. We are therefore not persuaded that Eppstein's device meets the means-plus-function limitation at issue.

In sum, we do not agree with the Examiner that Eppstein meets the limitation in claim 14 requiring the claimed device to have "a means for rupturing the rupturable covering and positively displacing the release formulation through the opening at the first end." We therefore reverse the Examiner's rejection of claim 14, and its dependent claims 15-18, 20-29, 35, 36, and 39 as anticipated by Eppstein.

OBVIOUSNESS -- KRULEVITCH AND SANTINI

ISSUE

Claims 19 and 42-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Krulevitch and Santini (Ans. 4-5).

The Examiner cites Krulevitch as teaching an "array of discrete microtubes (97) defining a reservoir (86-90), a release formulation (103), and means for dispensing the release formulation (81-85) by positive displacement of a barrier material (98-102) by an expanding material (81-85) by application of heat from a resistive heating element (81'-85')" (*id.* at 4 (citing Krulevitch, Figures 7A and 7B)). The Examiner concedes that Krulevitch "does not disclose the material of the microneedles being made of a metal, or a rupturable metal foil covering over the distal end of the microneedles" (*id.*).

To meet the missing limitation, the Examiner cites Santini as disclosing "a microreservoir array which is covered by a metal foil where the array is made of a biocompatible material (copper or gold, for example)" (*id.*). The Examiner concludes, based on the references' teachings, that one

of ordinary skill in the art would have considered it obvious "to place a metallic cover over the microneedles in order to prevent leakage of the reservoirs or contamination of the reservoir contents" (*id.* at 4-5).

Appellants contend that the Examiner has failed to make a prima facie case of obviousness (App. Br. 8-12). Specifically, Appellants argue, "[t]he Examiner has not set forth the required showing that all elements of Applicants' claim 19 are included in the prior art or would be combined in the fashion claimed" (*id.* at 10). Moreover, Appellants urge, "the Examiner has not set forth a showing as to why one of ordinary skill in the art would combine Krulevitch and Santini to derive Applicants' particularly claimed device" (*id.* at 11).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the Examiner has made a prima facie case that Krulevitch and Santini would have rendered a device having all of the elements recited in claim 19, in the configuration recited in the claim, obvious to a person of ordinary skill in the art.

FINDINGS OF FACT

11. Claim 19 recites a device similar to that of claim 14. The device has an array of microtubes, each microtube having a reservoir that contains a release formulation, the chemical molecules being contained in the release formulation. Each microtube's reservoir has a rupturable covering at one end.

Like the device of claim 14, the device of claim 19 has "a means for rupturing the rupturable covering and positively displacing the release formulation through an opening at the first end, to release the chemical molecules."

Claim 19 recites that the rupturing means has a layer of material which can be activated to expand upon application of heat by a resistive heating element or resistive coating. The expanding material is distal to the rupturable covering, and the release formulation is positioned between the expanding material and rupturable covering.

12. Krulevitch discloses methods of providing "integrated, low power pumps and valves for manipulating fluids in micro-devices" (Krulevitch, col. 1, ll. 47-49). Figures 7A and 7B, reproduced below, "illustrate[] top and side views of a microsyringe array application, such as transdermal drug delivery via microneedle" (*id.* at col. 2, ll. 65-67):

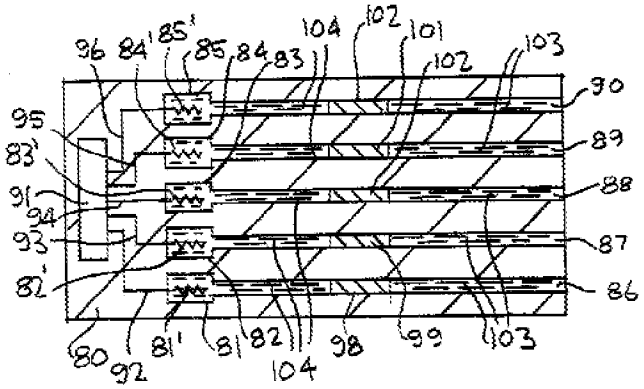


FIG. 7A

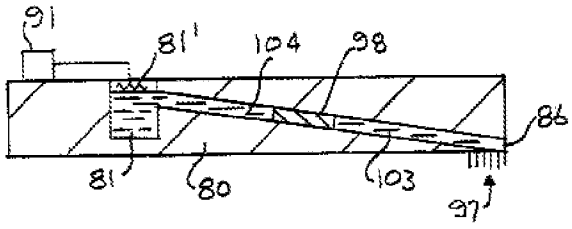


FIG. 7B

Figures 7A and 7B show:

> A . . . substrate **80** [which] is provided with a plurality of thermopneumatic chambers which may include resistive heaters **81'-85'** and indicates at **81**, **82**, **83**, **84** and **85** each chamber connected to a respective channel **86**, **87**, **88**, **89** and **90** formed in the substrate **80**. Each chamber **81-85** is connected to a programmable chip or microchip controller **91** via leads **92**, **93**, **94**, **95** and **96**. Channels **86-90** are each provided at an outer end with a plurality of microneedles **97** (see FIGS. 7B) and each channel **86-90** contains a piston **98**, **99**, **100**, **101** and **102** and is provided with a desired reagent **103** intermediate pistons **98-102** and microneedles **97**. The reagent **103** in each of the channels **86-90** may be the same or different, depending on the desired application. Each channel **86-90** contains a driving or actuation fluid **104** located intermediate pistons **98-102** and thermopneumatic chamber **81-85**.

(Krulevitch, col. 8, ll. 14-30.)

13. Krulevitch describes the operation of the device shown in Figures 7A and 7B as follows:

> In operation, one or more resistive heaters **81'-85'** heat fluid in thermopneumatic chambers **81-85** which cause the expansion of the driving fluid **104** and movement of one or more pistons **98-102** along channels **86-90** forcing the desired reagent **103** toward microneedles **97** for delivery of the reagent to a patient or other point of use.

(Krulevitch, col. 8, ll. 31-36.)

14. Santini discloses "[m]icrochip devices . . . which can accurately deliver drugs and other molecules at defined rates and times according to the needs of the patient or other experimental system" (Santini, col. 3, ll. 9-12).

15. Santini discloses that each microchip device "consists of a substrate, reservoirs, and a release system containing or enclosing the molecules to be delivered. Devices which control the release time of the molecules may

include reservoir caps. Active devices may include control circuitry and a power source" (Santini, col. 3, ll. 44-48).

16. Santini discloses that "[i]n the passive timed release drug delivery devices, the reservoir caps are formed from a material that degrades over time, or does not degrade but is permeable to the molecules to be delivered. These materials are preferably polymeric materials" (Santini, col. 5, ll. 30-34).

17. Santini discloses:

> In the active timed release devices, the reservoir caps consist of thin films of conductive material patterned in the shape of anodes surrounded by cathodes. Any conductive material that can oxidize and dissolve in solution upon application of an electric potential can be used for the fabrication of the anodes and cathodes. Examples of such materials include metals such as copper, gold, silver, and zinc, and some polymers . . . . The anode is defined as the electrode where oxidation occurs. The portion of the anode directly above the reservoir oxidizes and dissolves into solution upon the application of a potential between the cathode and anode. This exposes the release system to the surrounding fluids and results in the release of the molecules.

(Santini, col. 5, l. 64, through col. 6, l. 14.)

PRINCIPLES OF LAW

> In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. "[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references."

In re Fritch, 972 F.2d 1260, 1265 (Fed. Cir. 1992) (citations omitted, bracketed material in original).

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, ___, 127 S. Ct. 1727 (2007), the Supreme Court reaffirmed that it is obvious to choose from among known solutions to a problem recognized in the art:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that is was obvious under § 103.

Id. at 1742.

The Supreme Court also noted that the analysis under 35 U.S.C. § 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 1741. The Court further advised that "[a] person of ordinary skill is . . . a person of ordinary creativity, not an automaton." *Id.* at 1742.

Emphasizing the flexibility required in obviousness analyses, the Court further noted that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." *Id.* at 1742-1743 (citations omitted).

While it focused on the flexibility of the analysis, the Court nonetheless did not dispense with the premise that a conclusion of

obviousness requires some explicit rationale for practicing the claimed subject matter:

> [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does* . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 1741 (emphasis added); *see also* 1740-41 (requiring a determination of "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue") (emphasis added).

Accordingly, as our reviewing court has stated, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

ANALYSIS

We agree with Appellants that the Examiner has not made a prima facie case that Krulevitch and Santini would have rendered a device having all of the elements recited in claim 19, in the configuration recited in the claim, obvious to a person of ordinary skill in the art.

Like claim 14, claim 19 recites that its device has "a means for rupturing the rupturable covering and positively displacing the release formulation through the opening at the first end, to release the chemical molecules" (FF 11). As discussed above, when that means-plus-function limitation is viewed consistently with the Specification, it requires the device to have a single means capable of accomplishing both the rupturing of the cover and the positive displacement of the release formulation.

By its terms, claim 19 limits the rupturing means to a thermally-driven expansion material (FF 11). As the Examiner points out, Krulevitch uses a thermally-activated expanding fluid to drive the medicament out of the reservoirs in its device, through the attached microsyringes (FF 12-13).

However, even assuming for argument's sake that an ordinary artisan would have been prompted, as posited by the Examiner, to cover Krulevitch's microneedles with Santini's metallic covers to prevent leakage and/or contamination, Santini discloses that its metallic reservoir covers are provided as electrodes that rupture when an electric potential is applied to them (FF 17). Thus, following Santini's teachings and applying metallic covers to Krulevitch's microneedles would result in a device having separate means for rupturing the rupturable covering, and positively displacing the release formulation from the reservoirs. The combination of Krulevitch and Santini posited by the Examiner would therefore not result in the device recited in claim 19, which requires a single means that both ruptures the cover, and positively displaces the release formulation.

In sum, we do not agree with the Examiner that Krulevitch and Santini would have rendered a device having all of the elements recited in claim 19, in the configuration recited in the claim, obvious to a person of ordinary skill in the art. We therefore reverse the Examiner's rejection of claim 19, and its dependent claims 42-47, as obvious over Krulevitch and Santini.

OBVIOUSNESS -- EPPSTEIN AND THEEUWES

Claims 40 and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Eppstein and Theeuwes (Ans. 5). The Examiner finds that Eppstein differs from claims 40 and 41 in that Eppstein "do[es] not teach the use of a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation" (*id.*).

The Examiner cites Theeuwes to meet that limitation, and concludes that a person of ordinary skill in the art would have considered it obvious "to combine the osmotic delivery system of Theeuwes as an alternate 'small pump' with the micro needle array of Eppstein in order to facilitate expansion of the expandable member without electronics" (*id.*).

Claims 40 and 41 both depend, ultimately, from claim 14, and require all of the limitations of claim 14. As discussed above, Eppstein does not meet the limitation in claim 14 requiring the device to have a "means for rupturing the rupturable covering and positively displacing the release formulation through the opening at the first end."

Having reviewed the Theeuwes reference, we do not see, and the Examiner does not point to, any teaching in Theeuwes' disclosure of osmotic dosage devices that remedies Eppstein's failure to meet the means-plus-function limitation discussed above. Thus, the combined disclosures of the references do not disclose or suggest all of the limitations recited in claims 40 and 41. We therefore reverse the Examiner's rejection of claims 40 and 41 as being obvious over Eppstein and Theeuwes.

SUMMARY

We reverse the Examiner's rejection of claims 14-18, 20-29, 35, 36, and 39 under 35 U.S.C. § 102(e) as being anticipated by Eppstein.

We reverse the Examiner's rejection of claims 19 and 42-47 under 35 U.S.C. § 103(a) as being unpatentable over Krulevitch and Santini.

We reverse the Examiner's rejection of claims 40 and 41 under 35 U.S.C. § 103(a) as being unpatentable over Eppstein and Theeuwes.

REVERSED

cdc

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